IN THE FEDERAL DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA
Greenville Division

UNITED STATES OF AMERICA EX REL REYNOLD A. MCCLAIN, RPH. Plaintiff, vs. NUTRITIONAL SUPPORT SERVICES, LP Defendant.	)	CASE NO.: 6:17-CV-2608-AMQ

ORIGINALLY FILED IN CAMERA AND UNDER SEAL

FIRST AMENDED COMPLAINT

(False Claims Act, 31 U.S.C. §§3729-3733)

None of the allegations set forth in this Complaint are based on a public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative or General Accounting Office report, hearing, audit or investigation, or from the news media.

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PRELIMINARY STATEMENT

This lawsuit is based on the submission of false claims by Nutritional Support Services, LP ("NSS"), or its clients, various nursing homes and assisted living facilities within the State of South Carolina and perhaps in other states, specializing in the provision of long term care, to insureds of *inter alia* the federal Medicare, TriCare, Medicaid and Federal Employees Health Benefits Programs ("FEHPB") (collectively hereinafter "Federal Healthcare Programs" or "Federal Payers").

Responsibility for these false claims lies with the Defendant in this matter, NSS, doing business as "Network Healthcare" of 1200 Woodruff Road, Suite C28, Greenville, SC, 29607. There, NSS operates an institutional wholesale pharmacy, chiefly providing prescription medications to health care facilities and organizations that provide long-term nursing care throughout South Carolina, most notably to National Healthcare Corporation ("NHC") facilities in the state. NSS provides similar services in other states from other locations. Management at the Greenville location includes NSS employees, James L. "Jimmy" Sain, a registered pharmacist and Wayne Adams, Network Healthcare's Pharmacy Manager, Defendant Sain's

nephew and the Relator's immediate supervisor. Both had knowledge and were complicit of the scheme described herein.

In thousands of cases, NSS has charged the Federal Healthcare Payer Programs for medications dispensed to federal beneficiaries using fraudulent NDC numbers that resulted in inaccurate and illegal compensation to NSS as Claimant. The medications provided to the facilities and subsequently to federal insureds, were most often, but not in all cases, a less-expensive generic than that medication charged to the Federal Payer and/or other third-party indemnitors, NSS thereby having a far lower cost basis in the drugs billed and collecting on the claims at the expense of the Federal Healthcare Programs. NSS, to its benefit, was compensated to excess based upon the actual medication administered having a lower cost basis that the one billed on the claims forwarded to the insuring Federal Payer. In the minority of cases wherein a clearly less expensive generic alternative was not substituted, NSS in all cases billed using an NDC that did not match that of the medication actually reaching the patient.

As such, NSS knowingly presented, or caused to be presented, numerous fraudulent claims for payment to the Federal Healthcare Programs, knowingly certified, or caused to be certified, false records to get fraudulent claims paid, and knowingly concealed, or caused to be concealed, its obligation to repay and return those Federal Payers' funds, to which it was not rightfully entitled in its provision of prescription drug services. Each such claim represents an independent violation of the False Claims Act at 31 U.S.C. § 3729 et seq. as pled, *infra*. Additionally, the Relater was pretextually terminated by NSS in retaliation for bringing the fraud to the attention of Manager, James L. Sain, RPh and attempting to correct the fraud.

The Relator, Reynold L. McClain, RPh., acting on behalf of and in the name of the United States of America, brings this civil action under the *qui tam* provisions of the False Claims Act, 31 U.S.C. §§3729-3733, and alleges as follows:

JURISDICTION AND VENUE

1. That this Court has jurisdiction over this Complaint's parties and subject matter pursuant to 28 U.S.C. §§1331 and 1345, and false claims jurisdiction under 31 U.S.C. §3732(a) as NSS transacts business from its office in Greenville County, marketing to other areas and having substantial contacts throughout the State of South Carolina chiefly through contracting nursing homes and assisted-living facilities. This Court has supplemental jurisdiction over any related state law claims pursuant to 28 U.S.C. § 1367.

2. That virtually all of the Federal Payer Program beneficiaries on whose behalf NSS filed false claims for payment were South Carolina residents, although residents of other states were also involved. State Medicaid funds were also improvidently billed and fraudulently claimed as reimbursement, as many of the involved nursing home and assisted living facility patient met the income and asset tests requirements to qualify for Medicaid after exhausting their Medicare long-term care benefits (100 days). Additional remuneration in excess of fair market value inured to the benefit of NSS as a result of the fraud here and likely in other states.

3. That this is an action to recover damages and civil penalties brought by Pharmacist Reynold A. "Rey" McClain (hereinafter "Relator"), an individual, on behalf of the United States of America against his former employer, NSS, arising from the unlawful scheme and conspiracy to defraud the United States of America and the Federal Healthcare Programs, in particular, through submission of false and fraudulent Medicare, TriCare, FEHBP and Medicaid claims. All were submitted for reimbursement to the United States Government (including state

money contributions in the case of Medicaid insureds) in violation of the False Claims Act, as amended 31 U.S.C. §3729, *et seq*. ("False Claims Act"). Relator brought up his recognition of the scheme to NSS Management (Sain), who promised him it would be remedied, yet to this day, the false claims persist in being filed. Further, Sain by way of pretext terminated Relator's employment based upon his receipt of a legacy medication prescribed for him by a physician (celecoxib) from a fellow employee, when in actuality, Relator was terminated in retaliation, based upon his knowledge of, objection to, and failure to participate in the scheme.

4. That all the alleged acts pled herein arose in the State of South Carolina, although citizens of Georgia, North Carolina and possibly of other states are also likely involved, Relator, by information and belief, of the opinion that NSS provided pharmacy service to facilities in nearby states through other locations and that the fraud is widespread.

5. That NSS is a Tennessee Limited Partnership with its principle place of business at 9000 Executive Park Drive, Suite A-301, Knoxville, TN, 37923-4685 and is authorized to do business in this state. Accordingly, false claims venue in this district is proper also pursuant to 31 U.S.C. §3732(a), 28 U.S.C. §1391(b) and (c). **The physical address of NSS d/b/a Network Healthcare in South Carolina is 1200 Woodruff Road, Suite C28, Greenville, SC, 29607.**

6. That to Relator's knowledge, jurisdiction here is not barred by 31 U.S.C. §3730(e), nor the parallel provisions of any applicable state false claims acts: there is no civil suit, criminal or administrative proceeding involving the allegations and transactions herein to which the government is a party; there has been no "public disclosure" of these allegations or transactions; and in any event, Relator is an original source of the information contained herein.

PARTIES

7. That to Relator's knowledge NSS has no False Claims Act history and is a wholly-owned subsidiary of National HealthCare Corporation (NHC), 100 East Vine Street, Murfreesboro, TN 37130, publicly-traded on the New York Stock Exchange and with a market capitalization in excess of $1.1 billion.

8. That Relator is a registered pharmacist and former dispensing employee of NSS who has unique first-hand knowledge of its unlawful practices, including, with specificity, personal knowledge of its systematically defrauding of the Federal Healthcare Programs through its dispensing and filing claims for medications not having correct National Drug Code ("NDC") numbers.

9. That the Food and Drug Administration requires that every drug manufactured and dispensed have its own unique NDC. It is a violation of federal and state law and professional regulations and practice standards to dispense a drug not matching the NDC on the prescription label and to bill as if it did. Dispensing an incorrect medication can also be obviously unsafe to the patient receiving it.

10. That by regulation and statute, the Center for Medicare and Medicaid Services ("CMS") payments to pharmacies for prescription medications are predicated upon the NDC of the drug dispensed by the pharmacy. When a pharmacy fills or refills a prescription , CMS requires that it submit an accurate Prescription Drug Event ("PDE") Record, submission of same a condition of payment requiring certification to CMS of the NDC of the medication dispensed.

11. That instantly, NSS, by way of PDE Records submitted fraudulent claims to the Federal Payers for medications having NDCs that were not identical to those dispensed to the patient-insureds.

12. That while NSS dispensed on a routine seven (7) day cycle, the fraudulent medications were utilized when a patient-insured required medication immediately and before their routine maintenance medications could be entered into and dispensed using NSS' automated packaging system. Those initially provided medications to all newly-serviced patients and those medication changes made at any time by an existing patient's treating physician were and are in virtually all cases, substituted with less expensive generic medications that have NDCs different than those claimed for billing purposes.

13. That NSS used a machine-generated solid white label and green notice sticker placed on the medications fraudulently dispensed explaining that, "THIS IS THE SAME MEDICATION YOU HAVE BEEN GETTING. COLOR, SIZE OR SHAPE MAY APPEAR DIFFERENT". The solid white label included the truthful NDC of the medication dispensed while another yellow and white label displayed the NDC of the medication actually claimed on the HCFA 1500 form or electronic equivalent, that latter medication to be later dispensed by the "TCGRX," the automated packaging system used to dispense the patient-insured's maintenance medications.

14. That NSS then fraudulently and despite it being a condition of reimbursement by CMS, certified to the truth and accuracy of the NDC of the medications dispensed for use by the Federal Program insureds (despite its not being the one initially received by the patient), receiving payment for the medication later dispensed correctly once the patient was synchronized on the TCGRX automated system. CMS will not, absent fraud and concealment of the medication actually dispensed, pay a claim falsely reporting the NDC of the drug dispensed.

15. That NSS at its Greenville location and likely at others, since at least May 2011 to the present, has used its system to file thousands of false PDE claims with the Federal Healthcare

Programs and receive payment for those false claims and to avoid its repayment obligation to them, all the while potentially jeopardizing patient safety, same occurring with the knowledge and approval of its management.

IN CAMERA REVIEW

16. That under the provisions of 31 U.S.C. §3730(b)(2), this Complaint is to be filed *in camera* and is to remain under seal for a period of at least sixty (60) days and shall not be served on the Defendant until the Court so orders. The Government may elect to intervene and proceed with the action within sixty (60) days after it receives both the Complaint and the material evidence and information establishing this cause of action. Here, the government has elected not to immediately intervene.

17. That Relator, Reynold A. McClain, RPh., is a citizen and resident of the United States of America and the State of South Carolina suing in the name of and on behalf of the United States of America. From approximately May 24, 2011 until August 23, 2016, a period of over five years, Relator was an employee of NSS as an employed pharmacist, having personal knowledge of the operational, as well as billing and collections practices of NSS, where he staffed the pharmacy and filled medication prescriptions for nursing home and assisted living facility patients on orders from individual attending health care providers.

18. That Relator observed NSS' employees' practices as to the filing of claims with the Federal Healthcare Programs and knows that it is responsible for making, or causing to be made, and submitting, or causing to be submitted, fraudulent claims to them, for prescription medications administered to federal beneficiaries in nursing homes and/or assisted living facilities. The medications claimed were never received by the insureds, who instead were administered primarily, and in the majority of cases, lower-cost alternatives, in an attempt on the

part of NSS to receive increased remuneration and improve its profit. Relator is aware that these practices described herein and going back for a period of at least six, or more years, are ongoing as of the time of this Complaint's being filed through ongoing communication with current NSS employees. His assertions are based upon personal knowledge and he swears to the truth thereof under penalty of perjury.

19. That Relator has direct and independent knowledge within the meaning of 31 U.S.C. §3730(e)(4)(B) of the information on which the allegations set forth in this Complaint are based and he has voluntarily through his attorney provided the information to the Government by way of a Disclosure prior to filing this Complaint.

20. That as required by 31 U.S.C. §3730(a)(2), Relator has provided to the Attorney General of the United States and to the United States Attorney for the District of South Carolina, simultaneous with the initial filing of this Complaint, a statement of material evidence disclosing information related to the Complaint, the fraudulent billing and false claims submitted, or caused to be submitted by NSS.

21. That Defendant NSS provides medical and healthcare services to the public and receives substantial funds from the Federal Payer Programs. All submissions by it directly, or any of its customers acting upon representations made by NSS to the Federal Payer Programs for payment, or reimbursement, involve a representation and certification that this Claimant will abide by and has abided by, and that they individually will adhere to and have adhered to, all of the statutes, rules, and regulations governing the Medicare, TriCare, FEHBP and Medicaid programs.

22. That all of the actions attributed to NSS in this Complaint were taken by its employees and/or agents, acting within the scope of their employment and/or agency and with

full knowledge of management, James L. "Jimmy" Sain participating personally in the fraud. It is believed that the involved facilities billing third party payers where innocent participants in the scheme as they did not realize that the generally more expensive medications actually claimed were never received by the patient-beneficiaries, who instead received in most cases, a less expensive generic substitute with a different NDC.

APPLICABLE REGULATORY BACKGROUND

23. That the United States Department of Health and Human Services (hereinafter "HHS") acting by and through the Centers for Medicare and Medicaid Services (hereinafter "CMS") is an agency of the United States of America responsible for administering the Federal Medicare and Medicaid Programs, *see 42 U.S.C. §1395, et seq.*, under which healthcare facilities and providers may be reimbursed with federal funds for services provided to eligible patients or Medicare and/or Medicaid beneficiaries.

24. That the United States Department of Health and Human Services (hereinafter "HHS") acting by and through CMS is an agency of the United States of America responsible for administering the federal Medicare Program, *see 42 U.S.C. §1395, et seq.*, under which healthcare facilities and providers may be reimbursed with federal funds for services provided to eligible patients, or Medicare beneficiaries.

25. That the Medicare Program which provides federal reimbursement for medically necessary services and supplies used by eligible persons, or Medicare beneficiaries ("beneficiaries" or "patients") was established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. §1395, *et seq*. Medicare health care reimbursement is governed by statute and by regulations issued by HHS. The program was designed to be a health insurance program and provide for payment of inpatient and outpatient medical services, including payment for the

filling of prescriptions and durable medical equipment to persons over 65 years of age and others qualifying by way of disability or certain diagnoses under its terms and conditions.

26. That under Medicare, CMS provides reimbursement for the use of approved prescription medications under more than one relevant Part of the program: NSS primarily receives reimbursement from Medicare under Parts A and D of the program. Under Part A, CMS reimburses claimants based upon actual cost data submitted by healthcare facilities in their Annual Medicare Cost Report to CMS. Relevant to this matter, same would be reported by a facility as drugs purchased from NSS (but in the case of initial or change-over NSS-provided medications, billed incorrectly). Under Medicare's Part D, a facility orders its medications from NSS and the latter then bills the Part D Provider ("PDP") for the drug. CMS advances funds monthly to the PDP on the condition that the latter accurately submits the price paid by it for each prescription dispensed to CMS. Instantly, NSS in many cases reported paying more for the drugs dispensed than it actually paid because it actually dispensed a less-expensive generic.

27. That the Medicaid program was similarly established in 1965 by Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v as a means-tested program providing health care to the indigent that is jointly funded by the state and federal governments through taxpayer revenue and administered by the individual states with CMS oversight and the provision of certain federal matching funds. It is overseen by DHHS through CMS and designed to assist states in providing medical care, including the filling of prescriptions, to the financially needy who meet its qualifications.

28. That under Medicaid, NSS would submit claims either directly to the State Department of Health and Human Services, or to a State-approved Medicaid Managed Care entity. These would be paid directly by either of the above according to an approved Medicaid

covered drug schedule. CMS makes quarterly monetary transfers to the state to reimburse it for the federal share of the Medicaid expenditures occurring during that time period (up to 40%). To receive such reimbursement, the state must submit a quarterly Medicaid expenditure report to CMS as to its Medicaid costs during that period.

29. That CMS is responsible for the administration of the Medicare Programs and contracts with private companies in each state known as "intermediaries" or "carriers" to administer Parts A and B of Medicare, Medicaid being similarly managed. In South Carolina, Medicare is administered by Palmetto Government Benefit Administrators ("Palmetto GBA") and certain managed care contractors, while Medicaid is now virtually entirely administered by managed care contractors through the S.C. Department of Health and Human Services. The FEHP is administered by the U.S. Office of Personnel Management to cover federal employees.

30. That TriCare (formerly CHAMPUS) is the civilian health and medical program of the United States' Uniformed Services and is administered by the Department of Defense ("DOD"). In response to the DOD Appropriation Act for Fiscal Year 1994, TriCare was implemented as a nationwide managed care program for Uniformed Services personnel to receive health care services, generally from non-governmental entities.

31. That when Pharmacies such as NSS request payment from Medicare, Medicaid, TriCare and/or the FEHP for services provided to these program's beneficiaries, they are required to submit their claim for payment to the relevant carrier on a proper claim form designated by CMS as the HCFA 1500, or more recently the CMS 1500 form. *See 42 C.F.R. §424.32*. Such claims are, in rare cases submitted on paper, but now far more frequently, electronically.

32. That under the FCA, 31 U.S.C. § 3729(a)(1)(A), "knowingly" presenting or

causing to be presented to the United States, any false or fraudulent claim for payment is a violation of federal law for which the government my recover three time the amount of damages it sustains and a civil monetary penalty of between $5500.00 and $11,000.00 per claim. Many states have parallel provisions. South Carolina does not.

33. That under 31 U.S.C. § 3729(a)(1)(B), "knowingly" making or causing to be made a false record or statement to get a false or fraudulent claim approved by the government is a violation of federal law for which the government my recover three time the amount of damages it sustains and a civil monetary penalty of between $5500.00 and $11,000.00 per claim. Many states have parallel provisions.

34. That under 31 U.S.C. § 3729(a)(1)(G), any person who "knowingly" makes, uses, or causes to be made, or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government is a violation of federal law for which the government may recover three time the amount of damages it sustains and a civil monetary penalty of between $5500.00 and $11,000.00 per claim. Many states have parallel provisions.

35. That a "claim" under the FCA includes any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient, if the government provides any portion of the money or property which is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 US.C. 3729(b)(2).

36. That to establish liability under the FCA[1], the government or a whistleblower (Relator) must prove:

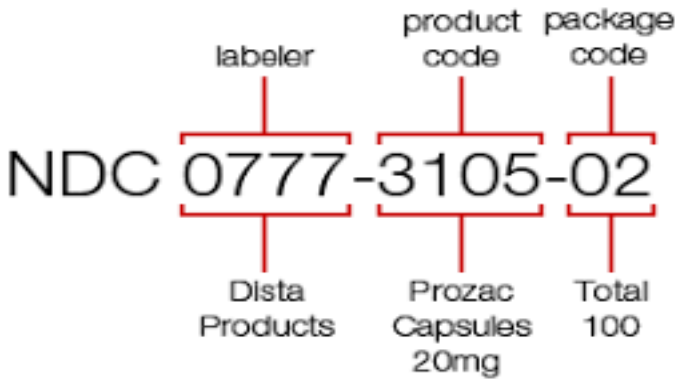
[1] 31 U.S.C. §§ 3729-3733.

a. That there was a "claim," statement, or conspiracy to defraud;
b. That the claim was submitted to the government or would be paid, in whole or in part, from funds from the government;
c. That the claim was submitted by defendant, or that defendant caused it to be submitted;
d. That the item or service represented in the claim was not provided as claimed or that the claim was false or fraudulent or the statement is "material to a false or fraudulent clam;" and
e. That the defendant knew or should have known that the claim or statement was false – including acting with deliberate ignorance or reckless disregard for the truth or falsity.

NATIONAL DRUG CODES

37. That the DHHS, through the Food and Drug Administration ("FDA"), requires that every drug have a NDC, 21 C.F.R. 207.25. The FDA assigns a NDC to every drug manufactured and sold to the public, 21 C.F.R. 207.35.

38. That the NDC is a unique three-segment number used as a universal product identifier for human drugs in this country. The code is present on all prescription medication packages and inserts in the United States. The three segments of the NDC identify the labeler or manufacturer, the product and the commercial package size.



The first set of numbers in the NDC identifies the labeler (manufacturer, packager, or distributor). The second set of numbers is the product code, which identifies the specific strength, dosage form (i.e. capsule, tablet, liquid) and formulation of the drug for a specific

manufacturer. The third set is the package code, which identifies package sizes and types. The labeler code is assigned by the FDA, while the product and package codes re assigned by the labeler.

39. That the FDA requires that every prescription drug "must have a bar code that contains at a minimum, the appropriate National Drug Code in a linear bar code." 21 C.F.R. 201.25(c)(1). Pharmacists nationwide use the NDC because it is the only medication identifier that confirms with certainty the medication being physically dispensed is in fact identical to the medication on the prescription label and identical to the medication being billed to the payer.

CMS PHARMACY PAYMENTS ARE BASED ON THE NDC

40. That CMS bases its payment for prescription drugs on the NDC number and NDC quantity for the drug dispenses and the NDC reported to the CMS must match the drug dispensed. Billing CMS based on an NDC number that is different from the NDC of the drug dispensed is a fraudulent billing.

MEDICARE

41. That DHHS mandates that CMS billings be based on certain medical data code sets, 45 C.F.R. 162.1000. For retail pharmacy drug transactions paid by CMS, HHS requires that the pharmacy use "NDCs , as maintained and distributed by HHS." 45 C.F.R. 162.1002(b)(2)(i) and (c)(1). Thus by regulation, the NDC is the basis for all CMS drug payment transactions.

42. That CMS has specific requirements for data that must be submitted by pharmacies in order to get paid by CMS. 42 C.F.R. 423.322 confirms that "Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law."

43. That pursuant to that regulation, on April 26, 2006, CMS issued a document entitled "Instructions: Requirements For Submitting Prescription Drug Event Data." CMS explains in the Introduction:

> **As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out provisions (citing 42 C.F.R. 423.322). This document describes how CMS will implement the statutory payments mechanisms by collecting a limited subset of data elements on 100 percent of prescription drug "claims" or events....**
>
> **Every time a beneficiary fills a prescription covered under Part D, plans must submit a summary record called the Prescription Drug Event (PDE) record to CMS. The PDE record contains prescription drug cost and payment data that will enable CMS to make payment to plans and otherwise administer the Part D benefit....**
>
> **The submitted data components fit together to allow calculation of payment under the four legislated payment mechanisms.**

44. That CMS goes on to specify the data elements that must be correctly reported in every PDE record submitted to CMS for payment: "In this section we list the required data elements that must be submitted in PDE records for payment."

45. That the PDE has a mandatory field to confirm that the drug was dispensed:

> **15. Product/Service ID**
> **This field identifies the dispensed drug using a National Drug Code (NDC). NDC will be reported in NDC11 format.**

46. That by filing the PDE record with CMS, the recipients of Medicare Part D payments are certifying that "the claims data" submitted is "accurate, complete and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement." 42 C.F.R. 423.505(k)(3).

47. That every drug has its own unique NDC, and the FDA requires that the label of every prescription drug product "must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code." 21 C.F.R. 201.25(b)(1)

and (c)(1). CMS requires as a condition of payment that the NDC of the drug dispensed be reported in the PDE. It is a violation of CMS's conditions of payment to submit a PDE record certifying to a false NDC that is not the NDC of the drug dispensed.

MEDICAID

48. That Congress specifically requires pharmacies to use NDC codes as the basis for Medicaid billing. Referring to the payment for outpatient drug through the Medicaid Drug Rebate Program, Congress mandated that

> **Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) [for single source drugs] and (B)(ii) [for multiple source drugs] using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.**

42 U.S.C. 1396r-8(a)(7)(C). The Secretary of DHHS has not specified any alternative to the NDC System.

49. That the Medicaid Drug Rebate Program requires drug manufacturers to enter into a national rebate agreement with CMS in exchange for State Medicaid coverage of the manufacturer's drugs. The Rebate Program helps offset the Federal and State costs of outpatient prescription drugs dispensed to Medicaid patients. All 50 states and the District of Columbia cover prescription drugs under the Medicaid Drug Rebate Program.

50. That the efficacy of the Rebate Program depends on the use of the correct NDC by the pharmacy and physician involved. Every State has instructions on how to comply with the requirements of the CMS Rebate Program. South Carolina has issued such guidance, same making it clear that valid NDC numbers are required and that billing for one manufacturer's product and dispensing another is prohibited. *See Exhibit 1*. CMS receives rebates from manufacturers for most outpatient prescriptions, same calculated using NDC codes. For the Rebate Program to function as Congress mandated, CMS must receive the correct NDC

information for every prescription claim. The NDC submitted to Medicaid must be the correct NDC for the drug and bottle size located on the package or container from which the medication was dispensed. The reporting of a NDC other than that of the drug dispensed violates a CMS condition for payment, for which a claim will be denied if CMS learns of the false NDC being utilized.

STATE PHARMACY BOARDS

51. That the various State Pharmacy Boards also require the use of the NDC. S.C. Code § 39-23-40(a)-(b) states:

> **A drug or device shall be deemed to be misbranded:**
> **(a) If its label is false or misleading in any particular.**
> **(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that reasonable variations shall be permitted under regulations issued by the Commissioner of Health and Environmental Control or issued under the Federal act. Provided, further, that in the case of any drug subject to § 39-23-50(b)(1), the label shall contain the name and place of business of the manufacturer of the finished dosage form and, if different, the name and place of business of the packer or distributor. For the purpose of this paragraph, the finished dosage form of a drug is that form of the drug which is, or is intended to be, dispensed or administered to the ultimate user upon prescription or as otherwise dispensed by the pharmacist.**

52. That within the S.C. Pharmacy Practice Act, S.C. Code § 40-43-86 informs strict labeling and dispensing requirements clearly mandating the inclusion of information conveyed in the NDC, such that failure to essentially meet the Rebate Requirements would be construed as a violation of state law.

BILLING CMS FOR A DRUG DIFFERENT FROM THE DRUG DISPENSED IS FRAUD

53. That the Medicare Program Integrity Manual ("MPIM") at §4.2.1 gives the following examples of Medicare fraud:

> **The most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the**

Medicare Program....Fraud may take such forms:....Altering claim forms, electronic claim records, medical documentation, etc., to obtain a higher payment amount.

It is axiomatic that billing CMS for supplies not provided constitutes Medicare fraud. Similarly, billing CMS for a product different from the product actually provided constitutes Medicare fraud.

54. That by regulation and instruction, CMS confirms it is a condition of payment for pharmacy drug claims that the NDC of the drug dispensed be reported in the PDE Record. CMS states that the NDC of the drug dispensed "must be submitted on the PDE records for payment." Every drug has its own unique NDC and it is a violation of CMS's condition of payment for a pharmacy to submit a claim with a NDC other than the NDC of the drug dispensed.

55. That similarly, the correct NDC is a statutory and regulatory condition of payment for Medicaid claims and rebate. 42 U.S.C. § 1396r-8(a)(7)(C). Every state recognizes this: *"The NDC submitted to Medicaid must be the actual NDC number on the package or container from which the medication was administered. It is considered a fraudulent billing practice to bill using an NDC other than the one administered."*

56. That this means pharmacies cannot bill CMS for one manufacturer's product while in fact dispensing another. If CMS audited a pharmacy and discovered the pharmacy was systematically submitting PDE claims with NDCs different from the NDC of the medication dispensed, CMS would deny the claims and insist on repayment. It is a 100% overpayment situation because such PDEs never should have been submitted and paid in the first place. Submitting a PDE with a false NDC constitutes a false claim because it is billing CMS for a product not dispensed and in violation of a CMS condition of payment.

57. That thus, the NDC of the manufacturer on the prescription label and the NDC of the manufacturer of the medication dispensed must match. If the manufacturer's NDC on the

label of the medication dispensed to the patient does not match the NDC of the dispensing manufacturer, CMS cannot and should not be billed as if they did match. To do so is to submit a false claim.

WHY NSS SUBSTITUTES LOWER COST GENERICS IN LIEU OF THE MAINTENCE PRESCRIPTION DRUG AS ORDERED DURING THE TRANSITION PERIOD TO TCGRX DISPENSING

58. A generic drug may be manufactured by several different manufacturers and each manufacturer has its own unique NDC for that same drug. A particular generic drug therefore has different NDCs, each NDC referring to a different manufacturer.

59. NSS aggressively shops for the lowest-priced generic versions of drugs and thus changes manufacturers on a frequent basis. When the manufacturer of a generic drug changes, the NDC changes as well. When a pharmacy decides to use a manufacturer for a generic drug that is different from the manufacturer NDC on the prescription label, it creates a non-match between the NDC on that label and the NDC for the product actually dispensed. This would ordinarily be immediately detected by automated label verification when the medication is dispensed by the TCGRX, or through visual verification by the NSS-employed pharmacist staff.

60. That by using less expensive generic medications in the transition period, prior to the patient's maintenance medications being converted to automatic processing via TCGRX, Network Healthcare is able to bill for more expensive medications than those actually dispensed. The substitution of a less-expensive generic medication, albeit the same medication prescribed for the patient/Federal Healthcare Program beneficiary, translates into a financial bonanza for NSS in dispensing non-matched drugs. Further this scam has now operated at least since 2011 and involves likely in excess of 1000 patients, who were victimized until NSS transitioned them

to TCGRX dispensing, Relator believing that thereafter those patients received the medication for which they were actually billed.

61. That transitional medications were at times the correct generic, but dispensed from a larger lot size, encompassing a lower fixed acquisition cost and resulting in another mechanism for financial windfall for NSS.

HOW NSS' FALSE CLAIMS JEOPARDIZE PATIENT SAFETY

62. That NSS' dispensing non-matched NDC medications is recklessly unsafe in many ways. Secretly substituting a different NDC drug for the NDC drug on the prescription label strips patients from of the protection provided by FDA patient level drug recalls, enables potentially fatal allergic reactions and potentially interferes with clinical efficacy and safety.

FDA PATIENT LEVEL DRUG RECALLS

63. That drug recalls are taken to remove a drug product from the market. Recalls are ordered by the FDA or done on a manufacturer's own initiative. The FDA classifies recalls in accordance with 21 C.F.R. § 7.41. A Class 1 recall, the most serious, is ordered when there is a reasonable probability that the use of, or exposure to a certain product will cause death or serious irreversible adverse health consequences. Of the Class I recalls between 2004 and 2011, 40% were because of contaminated drugs, 25% were because of wrong doses or release mechanisms and 35% were due to product mislabeling. In most quarters, there are well in excess of 100 drug recalls.

64. That in order for patients to benefit from recalls of potentially deadly drugs, the prescribing physician must be aware that the patient is taking the defective drug. The NSS scam strips patients of that protection by secretly substituting a different NDC medication for the NDC prescribed drug on the label. Because no healthcare personnel are aware that the patient is taking

that particular medication (which may have been recalled), there is no ability to protect the patient from its harmful effects.

ADVERSE DRUG REACTIONS AND ALLERGIES

65. That different manufacturers of the same drug have different prices, different packaging sizes and different ingredients. Different manufacturers use different excipients and dyes. These cannot be considered inert molecules and patients who are allergic to certain of these cannot take a medication from a manufacturer which uses those substances in their products. Reactions to those agents can range from rash to anaphylaxis to death.

66. That physicians and pharmacists cannot protect patients from such adverse events when a different NDC drug has been substituted for the medication actually prescribed and referenced on the label.

INTERFERENCE WITH CLINICAL EFFICACY AND/OR SAFETY

67. That the potency and bioequivalence of generic drugs is compared to the brand drug and not to one another.

68. That the FDA considers a generic drug to be interchangeable with a brand name drug if the generic is the "pharmaceutical equivalent" to the brand. A generic is the pharmaceutical equivalent if it has the same active ingredient strength, same route of administration and dosage, and same bioequivalence. The FDA allows the potency of a generic drug to fall within a bioequivalent range of 80% to 125% of the name brand drug.

69. That pharmaceutical equivalence is not therapeutic equivalence. Different generic drugs have different shapes, release mechanisms, and excipients (colors, flavors, preservatives), all of which lead to differences in their bioavailability (i.e., their potency or rate of absorption).

Switching from a generic at the top of the acceptable range to a generic at the bottom of that range increases the potential for clinical efficacy problems and serious adverse side effects.

70. That this is because once a patient is stabilized on one generic, switching to a different generic can precipitate a subclinical effect or an adverse safety event by under or over dosing, putting the safety of the patient at risk. This is most notable for medications with a narrow therapeutic range (that is with a minimum difference between minimum toxic and minimum effective concentration) where small changes in the potency or changes in the rate of absorption can change the serum concentration and result in serious therapeutic failures or adverse drug reactions. There is no assurance of comparable dosing in a switch from one generic to another, underscoring the recklessness of NSS in ignoring patient safety solely for profit-driven purposes.

71. That NSS is fully aware of the potential consequence of its scheme and despite clear implications as to patient safety, has perpetrated the fraud at the expense of the United States of America for over six years.

CLAIMS FOR RELIEF

FOR A FIRST CAUSE OF ACTION

VIOLATION OF FALSE CLAIMS ACT (31 U.S.C. §3729(a)(1)(A))
Claims for Payment in Violation of the False Claims Act

That Relator reaffirms and realleges the heretofore pled paragraphs as if set forth fully verbatim as related to this specific claim.

72. That this is a civil action by Relator Reynold A. McClain, RPh, acting on behalf of and in the name of the United States of America, against Defendant NSS for treble damages and monetary penalties pursuant to the FCA, 31 U.S.C. §§ 3729-33, as amended.

73. That from at the latest early 2011 and up to and including the present, a period of over six (6) years, but likely far longer, Defendant NSS, through the above-pled acts and omissions, knowingly caused to be presented for payment and approval, false and/or fraudulent claims to officers of the United States Government. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A).

74. That Federal Healthcare Program officials, their contractors, carriers, intermediaries and agents, paid and approved false claims for payment for such services that should not have been paid or approved.

75. That Defendant NSS through the means described above, deliberately and intentionally and despite Relator's caution to them, submitted, caused to be submitted, or assisted, or supervised the submission of fraudulent claims to the Federal Payer Programs, their officials, contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

76. That the Federal Healthcare Program officials, their contractors, carriers, intermediaries and agents, would not have paid the claims for services or otherwise reimbursed or advanced monies to Defendant NSS had they known the truth as to those claims' falsity.

77. That as a result of its plan and scheme, Defendant NSS received payments far in excess of those established for the medication they fraudulently dispensed during the transition period prior to patients being dispensed their maintenance medications through the TCGRX system.

78. That Defendant NSS concealed its illegal activities from the United States of America in an effort and for the specific purpose of defrauding the United States of America into paying Federal Payer claims that it otherwise would not have paid. Their submission of FEHBP,

Medicare, TriCare, and Medicaid claims involved a representation and certification that NSS would abide by and had abided by, and that it would adhere and had adhered to all of the statues, rules and regulations governing the Federal Healthcare Programs, which here it did not.

79. That as a result of the conduct of Defendant NSS, it has knowingly presented, or caused to be presented to an officer or employee of the United States of America, false or fraudulent claims for payment or approval in violation of 31 U.S.C. §3729(a)(1)(A).

80. That by reason of the above-descried presentment of false and fraudulent claims, the United States has suffered significant losses in an amount to be determined.

81. That the Government is entitled to treble damages based upon the amount of damages sustained by the United States of America as a result of violations of 31 U.S.C. §3729(a)(1)(A) by Defendant NSS.

82. That the government is entitled to a civil penalty between $5,500.00 and $11,000.00 as required by 31 U.S.C. §3729(a)(1) for each fraudulent claim submitted by Defendant NSS, of which, by Relator's estimate would exceed at a minimum, one thousand claims, notwithstanding any imposition of a "tainted claims" approach (which would increase that number) as has been recognized in some jurisdictions.

83. That Relator has some suspicion that this scheme is potentially being perpetrated through other NSS locations nationwide, with this claim and those following, thereby applicable to all of those entities as well.

84. That Relator is also entitled statutorily to reasonable attorney's fees and costs, pursuant to 31 U.S.C. §3730(d), hereby requesting same.

FOR A SECOND CAUSE OF ACTION

VIOLATION OF FALSE CLAIMS ACT (31 U.S.C. §3729(a)(1)(B))
Use of False Records or Statements

(AS TO DEFENDANTS ANMED AND AACC)

That Relator reaffirms and realleges the heretofore pled paragraphs as if set forth fully verbatim as related to this specific claim.

85. That this is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. § 3729-3733, as amended.

86. That through the above-described acts and omissions, and since at least early 2011 up to and including the present, Defendant NSS knowingly made, used, or caused to be made or used false records or statements to get a false or fraudulent claim paid or approved by the government to the damage of the United States of America in violation of 31 U.S.C. §3729(a)(1)(B). As a result of this illegal activity, Defendant NSS knowingly presented or caused to be presented to an officer or employee of the United States of America, false or fraudulent claims for payment or approval in violation of 31 U.S.C. §3729(a)(1).

87. That Federal Healthcare Program officials, their contractors, carriers, intermediaries and agents, paid and approved false claims for payment for such services that should not have been paid or approved.

88. That Defendant NSS through the means described above, deliberately and intentionally and despite Relator's caution to them, submitted, caused to be submitted, or assisted, or supervised the submission of fraudulent claims to the Federal Payer Programs, their officials, contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

89. That the Federal Healthcare Program officials, their contractors, carriers, intermediaries and agents, would not have paid the claims for services or otherwise reimbursed or advanced monies to the Defendants had they known the truth as to those claims' falsity.

90. That the United States of America has been damaged by reason of the above-described presentment of false records and statements in an amount to be determined.

91. That the Government is entitled to treble damages based upon the amount of damages sustained by the United States of America as a result of violations of law by these Defendants

92. That the government is entitled to a civil penalty between $5,500 and $11,000 as required by 31 U.S.C. §3729(a)(1) for each fraudulent claim of Defendant NSS, of which, by Relator's estimate would exceed at a minimum, one thousand claims, notwithstanding any imposition of a "tainted claims" approach (which would increase that number) as has been recognized in some jurisdictions.

93. That Relator has some suspicion that this scheme is potentially being perpetrated through other NSS locations nationwide, with this claim thereby applicable to all of those entities as well.

94. That Relator is also entitled statutorily to reasonable attorney's fees and costs, pursuant to 31 U.S.C. §3730(d), hereby requesting same.

FOR A THIRD CAUSE OF ACTION

VIOLATION OF FALSE CLAIMS ACT (31 U.S.C. §3729(a)(1)(G))
Use of False Record or Statement to Conceal a Payment Obligation

That Relator reaffirms and realleges the heretofore pled paragraphs as if set forth fully verbatim as related to this specific claim.

95. That this is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. § 3729-3733, as amended.

96. That Relator alleges that in performing the acts hereinbefore set forth, Defendant NSS knowingly made, used, or caused to be made and/or used false records or statements in

order to conceal, avoid and/or decrease the Defendant's obligation to pay or transmit monies of to offer certain reimbursement to the Federal Healthcare Programs to the damage of the United States of America in violation of 31 U.S.C. §3729(a)(1)(G).

97. That by reason of the above-described false records or statements, the United States of America has been damaged as a result of the violation of the False Claims Act in an amount to be determined.

98. That the Government is entitled to treble damages based upon the amount Of damages sustained by the United States of America as a result of violations of law by these Defendants.

99. That the government is entitled to a civil penalty between $5,500 and $11,000 as required by 31 U.S.C. §3729(a)(1) for each fraudulent claim of Defendant NSS, of which, by Relator's estimate would exceed at a minimum, one thousand claims, notwithstanding any imposition of a "tainted claims" approach (which would increase that number) as has been recognized in some jurisdictions.

100. That Relator has some suspicion that this scheme is potentially being perpetrated through other NSS locations nationwide, with this claim thereby applicable to all of those entities as well.

101. That Relator is also statutorily entitled to reasonable attorney's fees and costs, pursuant to 31 U.S.C. §3730(d), hereby requesting same.

FOR A FIFTH CAUSE OF ACTION

VIOLATION OF FALSE CLAIMS ACT (31 U.S.C. § 3730(h))
Individual Retaliation Involving Terms and Conditions of Employment
as to Relator McClain

That Relator reaffirms and realleges the heretofore pled paragraphs as if set forth fully verbatim as related to this specific claim.

102. Relator was at all time relevant to the allegations in this Complaint, an employee of Defendant NSS, who after learning of the fraudulent claims and scheme alleged herein confronted his employer, demanding that said practices, and other areas of concern be addressed

103. That despite Sain informing Relator in 2014 that it would do so if given thirty (30) days, Defendant NSS refused to change its fraudulent billing practices and address the procedure it utilized to transition new patients into the dispensing of their maintenance prescription medications by the TCGRX system

104. That in response to these requests and in light of their being refused, Relator was chastised and subjected to an objectively hostile work environment, harassed, threatened and discriminated against in his attempt to simply accurately identify, understand and stop the fraudulent claims and certain practices jeopardizing proper patient care, later being terminated based upon pretextual allegations (based upon his receiving a non-steroidal drug from a fellow employee) that were not the actual reason he was terminated.

105 That Defendant NSS, by way of Sain, filed a Pharmacy Board Complaint against the Relator, same summarily dismissed.

106. That based upon the above, Relator has been adversely affected in the terms and conditions of his employment by Defendant NSS because of lawful acts done by him in furtherance of this action at law to recover monies properly due to the United States of America, or at a minimum prevent further submission of false claims to it under similar circumstances.

107. That the totality of Relator's identification of, investigation of and attempted remediation of the scheme wherein Defendants Network Healthcare and Sain sought to

maximize their profits at the expense of the United States of America and its patients, particularly those federally insured through violation of 31 U.S.C. §3729(a)(1) in its relevant subparts, was the proximate cause and cause in fact of his being terminated as an employee of Network Healthcare.

108. That as such and under this section, Relator is entitled to all relief necessary to make him whole. Such relief shall include an offer of reinstatement with the same seniority status he would have had, but for the discrimination he was subjected to his later termination based upon his attempt to remedy the fraud, twice the amount of back pay based upon his prior compensation rate, interest on the back pay, and compensation for any and all special damages sustained as a result of his termination, including litigation costs and reasonable attorneys' fees.

WHEREFORE, Relator, on behalf of himself and the United States Government, pursuant to 31 U.S.C. §3730(c)(5) and (d) prays as follows:

(a) That this Court enter judgment against Defendant NSS in an amount equal to three times the amount of damages the United States Government has sustained because of Defendant's actions, plus a civil penalty of $5,500 - $11,000 for each action in violation of 31 U.S.C. §3729, and the costs and expenses of this action, with prejudgment interest, including the costs to the United States Government for its expenses related to this action;

(b) That if this action proceeds or the United States Government proceeds with any alternative remedy that Relator be awarded an amount the Court decides is reasonable for collecting the civil penalty and damages, between 15% and 30% of the proceeds of this action and/or any alternative remedy and/or the settlement of any such claim(s);

(c) That the United States Government and Relator receive all relief from Defendant, both at law and at equity, to which they may reasonably appear entitled, including all litigation costs and reasonable attorneys' fees incurred by the federal government and the Relator as provided pursuant to 31 U.S.C. § 3730(d) and other applicable law;

(d) That the Court compel a complete accounting from Defendant NSS of all Federal Healthcare Program beneficiaries who were victimized by its fraudulent billing scheme, thereafter applying the relevant civil monetary penalty to each applicable claim submitted on those beneficiaries' accounts;

(e) That Defendant NSS be required to pay Relator's Counsel's statutory attorney fees pursuant to 31 U.S.C. §3730(d); and

(f) Such further relief as the Court deems just and proper.

Respectfully submitted,

HINNANT MEDICAL & LAW OFFICES, LLC
ATTORNEYS AND COUNSELORS AT LAW

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Dated: June 19, 2018
Anderson, South Carolina